K062335
Page 1 of 2

SEP 14 2006

## 510(k) Summary

| | |
|---|---|
| SEDECAL SA<br>Pelaya 9- Poligono Industrial Rio De Janeiro<br>28110 –Algete<br>Madrid Spain<br>Tel (34) 91-628 0544/91-628 1592<br>Fax (34) 91-628 0574<br>(Foreign Manufacturer) | SEDECAL USA, Inc.<br>2910 N. Arlington Heights Rd.<br>Arlington Heights Illinois 60006<br>Tel 847-394-6960<br>Fax 847-394-6966<br>(Initial Importer)<br>Contact: Devan Moser |

July 20, 2006

1. Identification of the Device:
   Proprietary-Trade Name: SEDECAL X PLUS LP PLUS Universal Radiographic Systems
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: Sedecal URS X-Ray Units K012546.

3. Indications for Use (intended use) The SEDECAL X PLUS LP PLUS Universal Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. Description of the Device: SEDECAL X PLUS LP PLUS Universal Radiographic Systems are stationery units which operate from 120 or 220 V 50-60~ AC. The units utilize high frequency inverters. The usual safety precautions regarding the use of x-rays must be observed by the operator. This modified device employs new controls, including a touch screen and an infrared remote.

5. Safety and Effectiveness, comparison to predicate device. The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart, The Sedecal Portable X-ray Units with Detector

| Characteristic | Sedecal URS K012546 | SEDECAL X PLUS LP PLUS Universal Radiographic Systems |
|---|---|---|
| Intended Use: | General purpose diagnostic X-ray unit | SAME |
| Energy Source: | 120V, 230/240V(50/60Hz) Line or Battery Power | SAME |
| User Interface | Depends on Control Console option chosen. Mainly dedicated touch controls | Software Driven Touch Panel LCD, + remote control unit |
| Maximum output | Depends on model of generator chosen. Models available from 30 kW to 64 kW | SAME as original units. |
| Tube mount | Fixed with respect to receptor, arm can rotate. | Same |
| Receptor mount | Fixed on same column as tube head | SAME |
| Method of Control | Dedicated push button Controls | Software Driven Touch Panel LCD, remote control unit |
| Performance Standard | 21 CFR 1020.30 | SAME |
| Electrical safety: | UL 2601, IEC 60601-1 | SAME |

7. Conclusion

After analyzing bench, user, and standards testing data, it is the conclusion of Sedecal that the Sedecal Portable X-ray Units with Detector are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP 14 2006

SEDECAL SA
% Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K062335
Trade/Device Name: SEDECAL X PLUS LP PLUS Universal Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: August 8, 2006
Received: August 16, 2006

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K062335

Device Name: SEDECAL X PLUS LP PLUS Universal Radiographic Systems

Indications For Use:

Indications for Use: The SEDECAL X PLUS LP PLUS Universal Radiographic Systems are intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carolyn Y Neuland

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062335



**EXHIBIT 2**